K073178

510(k) Summary

Submitter Information

R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

Contact: Nancy Ring
Phone: 612-656-4533
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DEC 27 2007

Date Prepared: 11/12/07

Device Information

Proprietary Name:	HCT Extended Control
Common Name:	Hematology Controls
Classification	21 CFR 864.8625
Classification Name:	Hematology Quality Control Mixture
Product Code:	JPK
Device Class:	II
Panel:	Hematology (81)

Predicate Device

R&D Systems CBC-7 Hematology Control (K843962)

Description of Device

HCT Extended Hematology Control is an *in vitro* diagnostic reagent composed of human erythrocytes suspended in a plasma-like fluid with preservatives. It is an assayed whole blood control designed to monitor values obtained from automated, semi-automated and manual methods. It is sampled in the same manner as a patient specimen.

Intended Use:

HCT Extended is a control designed to monitor values obtained from automated, semi-automated and manual methods. Please refer to the assay table for specific instrument models.

Technological Comparison to Predicate

The new device has the same technological characteristics and intended use as the legally marketed predicate device. Both products are used to monitor values from automated, semi-automated and manual methods. Both are assayed controls that can be used to monitor hematocrit.

Summary of Performance Data

Laboratory testing of 3 validation lots has shown the HCT Extended Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. The HCT Extended Hematology Control passed the acceptance criteria of remaining within the assay range over the stated life of the product.

Substantial Equivalence Conclusion

The data demonstrates that the HCT Extended Hematology Control is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 2007

R & D Systems, Inc.
C/O Nancy C. Ring
614 McKinley Place, N.E.
Minneapolis, MN 55413

Re: k073178
Trade/Device Name: HCT Extended Hematology Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: November 12, 2007
Received: November 13, 2007

Dear Ms. Ring:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

Indications for Use

510(k) Number (if known): K073178

Device Name: HCT Extended Hematology Control

Indications for Use:

It is an established laboratory procedure to use a stable control to monitor the performance of diagnostic tests. HCT Extended Hematology Control is an assayed control designed to monitor values obtained from automated, semi-automated and manual methods.

For *in vitro* Diagnostic Use Only

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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